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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K113726

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5.1 Identification of the Device(s)

Common Name:	Creatinine Test
Trade Name:	epoc™ Creatinine Test
Classification Name:	electrode, ion based, enzymatic, creatinine
Device Classification:	2
Regulation Number:	862.1225
Panel:	Clinical Chemistry
Product Code:	CGL

Common Name:	Chloride Test
Trade Name:	epoc™ Chloride Test
Classification Name:	electrode, ion-specific, chloride
Device Classification:	2
Regulation Number:	862.1170
Panel:	Clinical Chemistry
Product Code:	CGZ

5.2 Identification of Predicate Devices

- i-Stat™ Chloride using i-Stat™ Model 300 Portable Clinical Analyzer
- Roche Cobas c 511/512 CREP2 Creatinine Plus ver. 2 assay

5.3 Description of the New Device

The epoc Chloride and Creatinine tests are being added as additional sensors to the existing single use test card that is used with the epoc Blood Analysis System. This test card is inserted into the epoc Reader and all analytical steps are performed automatically. Patient and user information may be entered into the mobile computing device (epoc Host) during the automated analysis cycle.

The epoc Blood Analysis System is an in vitro analytical system comprising a network of one or more epoc Readers designed to be used at the point of care (POC). The readers accept an epoc single use test card containing a group of sensors that perform diagnostic testing on whole blood. The blood test results are transmitted wirelessly to an epoc Host, which displays and stores the test results.
The epoc System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of whole blood.

The test card panel configuration currently includes sensors for Sodium Na, Potassium K, Ionized Calcium iCa, pH, pCO_2, pO_2, Lactate, Glucose and Hematocrit Hct. This submission adds Chloride and Creatinine to this list of approved tests.
To perform a blood test, a new test card is inserted into a card reader's card slot with white label face down. When fully inserted, the test card is automatically engaged in the reader.

The card insertion process:

- Brings the cards sensor module into contact with the reader's electrical contact array;
- Brings the card's measurement region, which is the fluidic channel above the sensor array, into thermal contact with the reader's heater assembly for heating the measurement region to 37°C;
- Actuates the opening of the fluidic valve in the card and causes delivery of calibrator fluid from the reservoir to the measurement region.

After calibration, and upon a prompt by the reader (LED visual and audio beep), the user introduces a blood sample for measurement through the blood sample port to the card's measurement region. When sensors are contacted by the blood sample they generate electrical signals proportional to analyte concentrations in the blood sample, which are transmitted wirelessly by the Reader to the epoc Host. The epoc Host displays and stores the blood test results.

The epoc Host will also display calculated values based on the new analytes:

Anion Gap: AGap = (Na+) - (**Cl-** + cHCO3-)

Anion Gap, K: AGapK = (Na+ + K+) - (**Cl-** + cHCO3-)

Estimated Glomerular Filtration Rate (IDMS-traceable MDRD type):
eGFR = 175 x (**Crea**-1.154) x (Age-0.203) x (0.742 if female, 1 if male)

Estimated Glomerular Filtration Rate, if African American (IDMS-traceable MDRD type):
eGFR-a = 175 x (**Crea**-1.154) x (Age-0.203) x (0.742 if female, 1 if male) x 1.212

Crea concentration is in units of mg/dL. Age and gender ("M" or "F") are user inputs. eGFR, eGFR-a are both reported on the epoc System. eGFR, eGFR-a values are not reported if age is less that 18 years old or greater than 70 years old.

Numeric values will be reported for values between 2-60 mL/min/1.73 m^2. Values >60 will be reported as > 60 mL/min/1.73 m^2. This range is based on the specific National Kidney Disease

Education Program (NKDEP) recommendation for reporting eGFR values. Please refer to the following web link: http://nkdep.nih.gov/lab-evaluation/gfr/reporting.shtml.

The following additional statement appears in our labeling:
eGFR > 60 does not exclude the possibility of mild renal disease. Further laboratory testing may be necessary to distinguish normal renal function from mild renal disease.

Addition of the epoc Chloride and Creatinine tests comprises three (3) changes to the epoc System:

1. Addition of the new sensors on the test card (described below);
2. Modification of the epoc System software application to accommodate the new tests (refer to Section 16 – Software);
3. Labeling changes including indications for use (refer to Section 04 – Indications for Use Statements and Section 13 – Proposed Labeling and Packaging).

5.4 Comparison of Characteristics To Predicate Devices

Tables Figures 5.1 and 5.2 itemize key characteristics of the epoc chloride and creatinine tests as part of the epoc device and their respective predicate devices. The chloride and creatinine tests are an addition to the previously cleared system. All other system features are the same as previously submitted on k061597, k090109 and k093297.

	epoc Blood Analysis System	**i-STAT Model 300**	
510(k) #	k113726	K001387	**Same / Different**
Item	Device	Predicate	
Intended use	The Chloride test, as part of the epoc Blood Analysis System, is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care . Chloride measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of electrolyte and metabolic disorders.	The test for chloride, as part of the i-STAT System, is intended for use in the *in vitro* quantification of chloride in arterial, venous, or capillary whole blood. Chloride measurements are primarily used in the diagnosis, monitoring, and treatment of electrolyte and metabolic disorders including, but not limited to, cystic fibrosis, diabetic acidosis, and hydration disorders.	similar
Where used	hospital, point of care	hospital, point of care	same
Sample type	Venous, arterial and capillary whole blood	Venous, arterial and capillary whole blood	same
Reportable range	65 – 140 mmol/L	65 – 140 mmol/L	same
Detection principle	The epoc Chloride test relies on ion selective membrane potentiometry.	The i-STAT Chloride test relies on ion selective membrane potentiometry.	same
Sample volume	At least 92 uL	100µL	same

Figure 5.1 – Table Comparing epoc Chloride Test Characteristics with Predicate Device

	epoc Blood Analysis System	Roche Cobas
510(k) #	k113726	K024098
Item	Device	Predicate
Intended use	The Creatinine test, as part of the epoc Blood Analysis System, is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care . Creatinine measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of certain renal diseases and in monitoring renal dialysis.	In vitro assay for the quantitative determination of creatinine in human serum, plasma and urine on Roche automated clinical chemistry analyzers.
Where used	hospital, point of care	hospital, laboratory
Sample type	Venous, arterial and capillary whole blood	Serum, Plasma, Urine
Reportable range	0.3 – 15.0 mg/dL	0.03 – 30 mg/dL
Detection principle	The epoc Creatinine test relies on enzymatic cascade reaction (creatininase, creatinase, sarcosine oxidase) leading to amperometric peroxide detection.	The Roche Creatinine test relies on an enzymatic cascade reaction (creatininase, creatinase, sarcosine oxidase) leading to peroxidase-catalyzed chromogenic peroxide detection.
Sample volume	At least 92 uL	2-5 uL

Figure 5.2 – Table Comparing epoc Creatinine Test Characteristics with Predicate Device

5.5 Summary of Non-Clinical Test Performance in Support of Substantial Equivalence

5.5.1 Aqueous precision

Experiments were performed in-house to demonstrate the precision of the epoc test methods. The table below shows the results of a twenty day precision study using performed on 3 lots using aqueous controls at two levels L1 and L3 for the blood gases, electrolytes and metabolytes.

	All lots	
Chloride [mM]	**L1**	**L3**
N	240	240
Mean	76.9	125.0
S_{WD}	0.35	0.61
S_{DD}	0.18	0.61
S_T	0.39	0.86
WD %CV	0.5%	0.5%
Total %CV	0.5%	0.7%

	All lots	
Creatinine [mg/dL]	**L1**	**L3**
N	239	241
Mean	0.71	5.50
SWD	0.030	0.197
SDD	0.017	0.112
ST	0.035	0.226
WD %CV	4.2%	3.6%
Total %CV	4.9%	4.1%

Figure 5.3 – Table – 20 Day Precision Study Data

5.5.2 Linearity/Reportable Range

This study was performed in-house using blood samples as per CLSI EP6-A recommendations for evaluation of linearity. A total of nine blood samples were prepared starting with two pools of blood, which were evaluated versus an in-house standard method with traceability to NIST standards. Regression analysis was performed as per CLSI EP6-A.

Chloride

Test Range	Slope	Intercept	R^2
65 - 144 mM	0.968	3.08	0.999

Creatinine

Test Range	Slope	Intercept	R^2
0.25 - 15.5 mg/dL	1.00	0.07	0.99

Figure 5.3 – Table - In House Whole Blood Linearity

This data supports the claimed reportable ranges of 65-140 mM for Chloride and 0.3 – 15.00 mg/dL for Creatinine.

5.5.3 Traceability

Chloride ion concentration values assigned to controls and calibrator fluids are traceable to NIST standards.

Creatinine concentration values assigned to controls and calibrator fluids are traceable to NIST standard SRM 967. The epoc Creatinine test is calibrated to an IDMS-traceable whole blood method and reports plasma equivalent concentrations.

5.5.4 Detection Limit

This study was performed in-house as per CLSI EP6-A recommendations for evaluation limits of detection and quantification. The low end of the reportable range for the epoc chloride test (65 mM) and the epoc creatinine test (0.30 mg/dL) are greater than or equal to the limit of detection and are statistically discernable from the limit of blank.

5.5.5 Analytical Specificity

Interference testing based on CLSI "Interference Testing in Clinical Chemistry; Approved Guideline", CLSI document EP7-A2. was performed in-house on the epoc chloride and creatinine sensors. In each of these tests a pooled human serum was aliquoted into two (2) samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated. The concentration of interfering substance considered as causing no clinically significant interference is defined as a bias (difference between the test and the control sample) of:

≤ 0.2 mg/dL for creatinine concentrations ≤2 mg/dL and ≤7.9% for creatinine concentrations >2 mg/dL ;

≤ 4.2% for chloride concentrations ≤125 mM and ≤5.2% for chloride concentrations >125 mM.

Clinically significant interfering substances for chloride are itemized below:

- ß-Hydroxybutyrate will have no significant effect up to 6.46 mM (67.2 mg/dL) after which it will increase the chloride reading by up to 0.63 mM/mM ß-Hydroxybutyrate.
- Bromide will have no significant effect up to 3.43 mM after which it will increase the chloride reading up to 9.36 mM/mM Bromide.
- Citrate will have no significant effect up to 2.36 (45.3 mg/dL) mM after which it will increase the chloride reading by up to 1.37 mM /mM Citrate.
- N-Acetylcysteine will have no significant effect up to 2.85 mM (46.4 mg/dL) after which it will decrease the chloride reading by up to 1.34 mM/mM N-Acetylcysteine.
- Salicylic acid will have no significant effect up to 2.55 mM (41 mg/dL) after which it will increase the chloride reading up to 1.66 mM/mM Salicylic acid.
- Thiocyanate will have no significant effect up to 2.50 (14.5 mg/dL) mM after which it will increase the chloride reading up to 1.66 mM/mM Thiocyanate.

The following levels of exogenous interferences were tested and found to be clinically insignificant:
1.324 mmol/L (20 mg/dL) acetaminophen, 3.62 mmol/L (65.2 mg/dL) acetylsalicylic acid, 342 µmol/L (6.8 mg/dL) Na ascorbate, 3.4 µmol/L (0.1 mg/dL) EDTA, 71 µmol/L methyldopa, 2.55 mmol/L (156 mg/dL) oxidized glutathione, 132 µmol/L (1.0mg/dL) hydroxyurea, 292 µmol/L (4mg/dL) isoniazid (nydrazid), +0.8% intralipid, 3 µmol/L (0.1 mg/dL) dobutamine, 5.87 µmol/L (0.1 mg/dL) dopamine, 86.8 mmol/L (400 mg/dL) ethanol, 105 µmol/L (0.44 mg/dL) fluoride, 133 µmol/L (0.4 mg/dL) formaldehyde, 55 mmol/L (990 mg/dL) glucose, 0.4 mmol/L (5 mg/dL) guaiacol, 3000 U/L heparin, 2.43 mmol/L (50 mg/dL) ibuprofen, 0.1 mmol/L (2.0 mg/dL) L-Dopa, 51.2 µmol/L (1.2 mg/dL) lidocaine, 71 µmol/L (1.7 mg/dL) methyldopa, 354 µmol/L (9.4 mg/dL) pentathol, 2.37 mmol/L (64 mg/dL) tolbutamide, 2.99 mmol/L (49.6 mg/dL) Iodide.

The following levels of endogenous interferences were tested and found to be clinically insignificant:
+342 µmol/L (+20.1mg/dL) bilirubin unconjugated, +342 µmol/L (28.8 mg/dL) bilirubin conjugate, +382 µmol/L (5.0 mg/dL) creatine, 102 mmHg CO_2, 13 mmHg CO_2, + 40 mmol/L bicarbonate , pH >8.0, pH < 6.8, 24%- 66% hematocrit, <6.0% protein,>8.0% protein, 1.4 mmol/L (23.5 mg/dL) uric acid. 6.6 mmol/L (74 mg/dL) lactate, 122 mmHg O_2, 28 mmHg O_2, 0.25 mmol/L (2.9 mg/dL) proline, 1 µmol/L (0.01 mg/dL) sarcosine, 42.9 mmol/L (258 mg/dL) urea.

Clinically significant interfering substances for creatinine are itemized below:

- Creatine will have no significant effect up to 116 µmol/L (1.52 mg/dL) after which it will increase the creatinine concentration by up to 0.0025 mg/dL creatinine per µmol/L creatine. The normal range of creatine in plasma is 8 – 31 µmol/L (0.1- 0.4 mg/dL) in males and 15 – 53 µmol/L (0.2 – 0.7 mg/dL) in females[15].
- Bilirubin conjugate will have no significant effect up to 104 µmol/L (8.76 mg/dL) after which it will decrease the creatinine concentration by up to

0.002 mg/dL creatinine per µmol/L bilirubin conjugate. The normal range of bilirubin conjugate is 0 - 3.4 µmol/L (0 - 0.2 mg/dL)[2].

- Bromide will have no significant effect up to 17.9 mmol/L after which it will decrease the creatinine concentration by up to 0.014 mg/dL creatinine per mmol/L bromide.
- Thiocyanate will have no significant effect up to 0.93 mmol/L (5.41 mg/dL) after which it will decrease the creatinine concentration by up to 0.142 mg/dL creatinine per mmol/L thiocyanate.
- Citrate will have no significant effect up to 19.9 mmol/L (382.1 mg/dL) after which it will decrease the creatinine concentration by up to 0.026 mg/dL creatinine per mmol/L citrate.
- Iodide will have no significant effect up to 0.007 mmol/L iodide (0.089 mg/dL) after which it will decrease the creatinine concentration by up to 28 mg/dL creatinine per mmol/L iodide.
- N-acetyl cysteine will have no significant effect up to 820 µmol/L (13.35 mg/dL) after which it will decrease the creatinine concentration by up to 0.26 mg/dL creatinine per mmol/L N-acetyl cysteine. It has been reported that 1 mM N-acetyl cysteine is therapeutically unattainable in plasma[8]. The therapeutic level for N-acetyl cysteine is 0.3 mM[16].

The following levels of exogenous interferences were tested and found to be clinically insignificant:
1.324 mmol/L (20 mg/dL) acetaminophen, 3.62 mmol/L (65.2 mg/dL) acetylsalicylic acid, 5 µmol/L (0.7 mg/dL) bacitractin, 30.2 µmol/L (1 mg/dL) ciprofloxacin, 48.6 µmol/L (1.75 mg/dL) Levofloxaxin, 342 µmol/L (6.8 mg/dL) Na ascorbate, 100 µmol/L (~2mg/dL) L-dopa, 3.4 µmol/L (0.1 mg/dL) EDTA, 105 µmol/L (0.441mg/dL) Na fluoride, 71 µmol/L (1.7 mg/dL) methyldopa, 2.55 mmol/L (156 mg/dL) oxidized glutathione, 2.55 mmol/L (78 mg/dL) reduced glutathione, 920 µmol/L (6.96 mg/dL) hydroxyurea, 292 µmol/L (4mg/dL) isoniazide (nydrazid), +0.8% (800 mg/dL) intralipid, 3 µmol/L (0.1 mg/dL) dobutamine, 5.87 µmol/L (0.1 mg/dL) dopamine, 86.8 mmol/L (400 mg/dL) ethanol, 133 µmol/L (0.4 mg/dL) formaldehyde, 55 mmol/L (990 mg/dL) glucose, 0.4 mmol/L (5 mg/dL) guaiacol, 3000 U/L heparin, 2.43 mmol/L (50 mg/dL) ibuprofen, 78.1 µmol/L (6.42 mg/dL) rifampicin, 51.2 µmol/L (1.2 mg/dL) lidocaine, 354 µmol/L (9.4 mg/dL) pentathol, 4.34 mmol/L (70 mg/dL) salicylate, 2.37 mmol/L (64 mg/dL) tolbutamide.

The following levels of endogenous interferences were tested and found to be clinically insignificant:
+342 µmol/L (+20.1mg/dL) bilirubin unconjugated, 100.26 mmHg CO2, 15.5 mmHg C02, + 48.2 mmol/L Bicarbonate , pH >8.0, pH < 6.8, 24% – 66% Hematocrit, <6.0% Protein, >8.0% Protein, 1.4 mmol/L (23.5 mg/dL) Uric Acid. 6.6 mmol/L (74 mg/dL) lactate, 132 mmHg O2, 22 mmHg O2, 0.25 mmol/L (2.9 mg/dL) proline, 1 µmol/L (0.01 mg/dL) sarcosine, 10.0 mmol/L (104 mg/dL)
ß-hydroxybutyrate, 42.9 mmol/L (258 mg/dL) urea.

5.6 Summary of Clinical Tests Submitted in Support of Substantial Equivalence

5.6.1 Method comparison with Predicate and Comparative Devices

We have performed side-by-side comparisons of the epoc System with the predicate devices and other comparative devices in clinical field trials. Venous, arterial, capillary samples were tested by a variety of potential end users. Multiple card lots and multiple epoc system readers and host computers were employed.

Method comparison studies for chloride were performed at two hospitals. Venous samples were compared with 2 non-point-of-care systems (2 serum methods). Venous, arterial and capillary patient samples were compared with a whole blood point-of-care system. Consolidated method comparison data versus the predicate device and comparative instruments are summarized in the tables 5.5 below.

	non-POC Systems*	Abbott i-STAT†
N	96	155
Sxx	0.6	0.9
Syy	0.6	0.8
slope	0.90	0.99
intercept	9.38	0.20
Syx	2.1	1.9
X min	71	69
X max	142	139
R^2	0.96	0.98
Mean Bias at 112 mM	-1.3	-1.0

Figure 5.5 – Table – Chloride Method Comparison Data

* Pooled venous sample data. Approximate equal number vs. Roche Cobas 6000, Siemens Advia
† Patient samples approximately equal numbers of venous, arterial and capillary samples versus Abbott i-STAT 300

Method comparison studies were performed at a hospital site comparing venous, arterial and capillary patient samples with a serum-based laboratory method. Consolidated method comparison data versus the predicate device are summarized in the tables 5.6 below.

Roche Cobas 6000*	
N	144
Sxx	0.10
Syy	0.30
slope	1.03
intercept	-0.10
Syx	0.45
X min	0.30
X max	14.80
R^2	0.99
Mean Bias at 1.25 mg/dL	-0.06

Figure 5.6 – Table – Creatinine Method Comparison Data

* Patient samples approximately equal numbers of venous, arterial and capillary samples

5.6.2 Blood Precision

Whole blood precision studies were performed at clinical sites to demonstrate precision when analyzed by end users. Normal and spiked level samples were tested injected by both syringes and capillary tubes.

User	QC Level	N	Mean	SD	%CV	Lot
Special Care Nursery RN 1	Normal syringe	10	102.11	1.01	1.0%	08-11250-00
Special Care Nursery RN 2	Normal syringe	10	102.58	0.53	0.5%	08-11244-00
Labor & Delivery RN 1	Normal syringe	9	108.80	1.25	1.2%	08-11243-00
Labor & Delivery RN 2	Normal syringe	10	109.10	0.99	0.9%	08-11244-00
Special Care Nursery RN 1	Spiked syringe	10	111.97	0.51	0.5%	08-11250-00
Special Care Nursery RN 2	Spiked syringe	10	112.29	0.66	0.6%	08-11243-00
Labor & Delivery RN 1	Spiked syringe	10	114.99	0.95	0.8%	08-11243-00
Labor & Delivery RN 2	Spiked syringe	10	114.18	0.49	0.4%	08-11250-00

Figure 5.7 – Table – Chloride Blood Precision Site 1

User	QC Level	N	Mean	SD	%CV	Lot
Respiratory Therapist 1	Normal syringe	10	107.43	0.34	0.3%	08-11250-00
Client Services Rep	Normal syringe	11	105.93	0.41	0.4%	08-11243-00
Anesthesia Tech 1	Normal syringe	10	105.81	0.39	0.4%	08-11244-00
Phlebotomist 1	Normal syringe	10	109.31	0.31	0.3%	08-11243-00
OP Surgery Tech 1	Normal syringe	10	106.46	0.40	0.4%	08-11243-00
OP Surgery Tech 2	Normal syringe	10	107.43	0.83	0.8%	08-11243-00
Phlebotomist 2	Normal syringe	10	104.57	0.33	0.3%	08-11243-00
Phlebotomist 3	Normal syringe	10	107.16	0.79	0.7%	08-11245-00
Respiratory Therapist 1	Spiked syringe	10	135.18	0.74	0.5%	08-11243-00
Client Services Rep	Spiked syringe	10	131.07	0.75	0.6%	08-11250-00
Anesthesia Tech 1	Spiked syringe	10	131.27	1.79	1.4%	08-11243-00
Phlebotomist 1	Spiked syringe	10	136.25	1.55	1.1%	08-11250-00
OP Surgery Tech 1	Spiked syringe	10	115.86	0.37	0.3%	08-11243-00
OP Surgery Tech 2	Spiked syringe	10	115.87	1.19	1.0%	08-11245-00
Phlebotomist 2	Spiked syringe	10	115.15	0.55	0.5%	08-11243-00
Phlebotomist 3	Spiked syringe	10	117.12	0.81	0.7%	08-11245-00
Client Services Rep	Normal capillary	10	106.31	0.56	0.5%	08-11250-00
Anesthesia Tech 1	Normal capillary	10	107.22	0.75	0.7%	08-11244-00
OP Surgery Tech 1	Normal capillary	10	106.74	0.84	0.8%	08-11244-00
Phlebotomist 2	Normal capillary	10	105.21	0.66	0.6%	08-11243-00
Client Services Rep	Spiked capillary	10	131.32	2.10	1.6%	08-11250-00
Anesthesia Tech 1	Spiked capillary	10	132.08	1.11	0.8%	08-11244-00
OP Surgery Tech 1	Spiked capillary	10	115.19	0.88	0.8%	08-11244-00
Phlebotomist 2	Spiked capillary	10	114.82	0.34	0.3%	08-11243-00

Figure 5.8 – Table – Chloride Blood Precision Site 2

User	Site	Sample	N	Mean	SD	%CV	Lot
Medical Technician 1	1	Normal syringe	10	0.64	0.03	5.3%	07-12137-00
Medical Technician 2	1	Normal syringe	10	0.69	0.07	9.7%	07-12137-00
Phlebotomist 1	2	Normal syringe	10	0.62	0.05	8.7%	07-12144-00
Phlebotomist 2	1	Normal syringe	10	0.56	0.05	8.6%	07-12136-00
Phlebotomist 3	2	Normal syringe	10	0.59	0.04	7.4%	07-12132-00
Phlebotomist 4	2	Normal syringe	10	0.65	0.05	7.7%	07-12137-00
Phlebotomist 5	2	Normal syringe	10	0.68	0.07	10.1%	07-12144-00
Respiratory Therapist 1	3	Normal syringe	9	0.64	0.03	4.3%	07-12136-00
Respiratory Therapist 2	3	Normal syringe	10	0.63	0.05	8.0%	07-12132-00
Respiratory Therapist 3	3	Normal syringe	10	0.48	0.04	8.8%	07-12144-00
Respiratory Therapist 4	3	Normal syringe	10	0.43	0.02	3.6%	07-12132-00
Specimen processor	1	Normal syringe	9	0.63	0.05	8.1%	07-12144-00
Medical Technician 1	1	Spiked syringe	10	1.70	0.09	5.2%	07-12144-00
Medical Technician 2	1	Spiked syringe	10	1.60	0.06	3.9%	07-12144-00
Phlebotomist 1	2	Spiked syringe	9	1.61	0.10	6.1%	07-12137-00
Phlebotomist 2	1	Spiked syringe	10	1.50	0.03	1.7%	07-12132-00
Phlebotomist 3	2	Spiked syringe	10	1.52	0.05	3.1%	07-12136-00
Phlebotomist 4	2	Spiked syringe	10	1.58	0.05	3.4%	07-12144-00
Phlebotomist 5	2	Spiked syringe	10	1.48	0.05	3.7%	07-12137-00
Respiratory Therapist 1	3	Spiked syringe	10	1.47	0.07	4.9%	07-12132-00
Respiratory Therapist 2	3	Spiked syringe	9	1.51	0.06	4.2%	07-12136-00
Respiratory Therapist 3	3	Spiked syringe	10	1.69	0.03	1.6%	07-12137-00
Respiratory Therapist 4	3	Spiked syringe	10	1.58	0.05	3.2%	07-12144-00
Specimen processor	1	Spiked syringe	10	1.61	0.10	5.9%	07-12137-00
Phlebotomist 1	2	Normal capillary	10	0.50	0.05	9.5%	07-12144-00
Phlebotomist 6	2	Normal capillary	9	0.55	0.04	6.5%	07-12144-00
Specimen processor	1	Normal capillary	10	0.52	0.02	4.3%	07-12132-00 (n=7) 07-12136-00 (n=3)
Phlebotomist 1	2	Spiked capillary	10	1.42	0.07	5.1%	07-12132-00
Phlebotomist 6	2	Spiked capillary	10	1.43	0.05	3.4%	07-12136-00
Specimen processor	1	Spiked capillary	10	1.52	0.05	3.4%	07-12144-00

Figure 5.9 – Table – Creatinine Blood Precision

Chloride				
All Users - All Sites Whole Blood	Normal Syringe	Spiked Syringe	Normal Capillary	Spiked Capillary
N - Tests	120	119	40	40
N - Runs	12	12	4	4
N - Replicates	10	10	10	10
Within-run				
Range	102.1-109.3	112.0-136.3	105.2-107.2	114.8-132.1
Mean	106.8	120.9	106.4	123.4
Avd SD W-R	0.63	0.86	0.70	1.11
CV% W-R	0.6%	0.7%	0.7%	0.9%

Creatinine				
All Users - All Sites Whole Blood	Normal Syringe	Spiked Syringe	Normal Capillary	Spiked Capillary
N - Tests	118	118	29	30
N - Runs	12	12	3	3
N - Replicates	10	10	10	10
Within-run				
Range	0.43-0.69	1.47-1.70	0.5-0.55	1.42-1.52
Mean	0.6	1.57	0.52	1.45
Avd SD W-R	0.05	0.06	0.04	0.06
CV% W-R	7.6%	3.9%	6.8%	3.9%

Figure 5.10 – Tables – Chloride and Creatinine Blood Precision Summaries

5.6.3 Aqueous precision

Aqueous precision studies were performed at clinical sites to demonstrate precision when analyzed by end users. Samples tested were commercially available blood gas, electrolytes and metabolites control fluids, L1, L2 and L3 (Eurotrol, The Netherlands).

User	QC Level	N	Mean	SD	%CV	Lot
Special Care Nursery RN 1	L1	15	76.65	0.35	0.5%	08-11243-00
Special Care Nursery RN 2	L1	15	76.69	0.35	0.5%	08-11243-00
Labor & Delivery RN 1	L1	15	76.47	0.85	1.1%	08-11244-00
Labor & Delivery RN 2	L1	15	76.60	0.40	0.5%	08-11243-00
Special Care Nursery RN 1	L2	15	98.20	0.36	0.4%	08-11250-00
Special Care Nursery RN 2	L2	15	98.47	0.30	0.3%	08-11244-00
Labor & Delivery RN 1	L2	15	98.66	0.43	0.4%	08-11243-00
Labor & Delivery RN 2	L2	15	98.17	0.50	0.5%	08-11250-00
Special Care Nursery RN 1	L3	15	123.30	0.65	0.5%	08-11250-00
Special Care Nursery RN 2	L3	15	123.29	0.26	0.2%	08-11250-00
Labor & Delivery RN 1	L3	15	123.49	1.86	1.5%	08-11250-00
Labor & Delivery RN 2	L3	15	123.70	0.52	0.4%	08-11243-00

Figure 5.11 – Table – Chloride Aqueous Precision Site 1

User	QC Level	N	Mean	SD	%CV	Lot
NICU RN 1	L1	15	76.26	0.71	0.9%	08-11250-00
Respiratory Therapist 1	L1	15	76.71	0.30	0.4%	08-11244-00
Client Services Rep	L1	15	76.73	0.40	0.5%	08-11243-00
Anesthesia Tech 1	L1	15	76.64	0.42	0.6%	08-11243-00
OP Surgery Tech 1	L1	15	76.12	0.43	0.6%	08-11250-00
OP Surgery Tech 2	L1	15	76.41	0.43	0.6%	08-11250-00
Phlebotomist 2	L1	15	76.26	0.24	0.3%	08-11243-00
NICU RN 2	L2	15	98.69	0.57	0.6%	08-11250-00
Respiratory Therapist 1	L2	14	99.02	0.29	0.3%	08-11244-00
Client Services Rep	L2	15	98.96	0.65	0.7%	08-11245-00
Anesthesia Tech 1	L2	14	99.10	0.18	0.2%	08-11244-00
Phlebotomist 1	L2	15	98.18	0.30	0.3%	08-11250-00
OP Surgery Tech 1	L2	15	98.38	0.74	0.8%	08-11250-00
OP Surgery Tech 2	L2	15	98.45	0.48	0.5%	08-11243-00
NICU RN 3	L3	15	125.39	0.89	0.7%	08-11250-00
Respiratory Therapist 1	L3	15	124.52	0.37	0.3%	08-11244-00
Client Services Rep	L3	14	123.43	0.59	0.5%	08-11250-00
Anesthesia Tech 1	L3	15	123.27	0.37	0.3%	08-11243-00
OP Surgery Tech 1	L3	15	123.07	1.10	0.9%	08-11250-00
OP Surgery Tech 2	L3	14	123.53	0.31	0.2%	08-11243-00

Figure 5.12 – Table – Chloride Aqueous Precision Site 2

User	QC Level	N	Mean	SD	%CV	Lot
Obstetrics RN 1	L1	15	0.70	0.04	5.6%	07-12130-00
Phlebotomist 1	L1	15	0.68	0.06	8.2%	07-12129-00
Respiratory Therapist 1	L1	15	0.64	0.04	6.6%	07-12136-00
POC Technician	L1	15	0.66	0.05	7.2%	07-12129-00
Obstetrics RN 2	L1	14	0.67	0.02	3.2%	07-12129-00
Phlebotomist 2	L1	15	0.64	0.05	8.3%	07-12132-00
Medical Technologist	L1	15	0.68	0.04	5.3%	07-12130-00
Obstetrics RN 3	L1	15	0.71	0.03	4.9%	07-12129-00
Obstetrics RN 1	L2	15	2.18	0.09	4.2%	07-12132-00
Phlebotomist 1	L2	15	1.91	0.07	3.5%	07-12130-00
Respiratory Therapist 1	L2	15	2.03	0.05	2.3%	07-12129-00
POC Technician	L2	15	1.90	0.06	3.2%	07-12130-00
Obstetrics RN 2	L2	15	2.12	0.11	5.0%	07-12132-00
Phlebotomist 2	L2	15	2.06	0.09	4.2%	07-12136-00
Medical Technologist	L2	15	2.15	0.09	4.3%	07-12136-00
Obstetrics RN 3	L2	15	1.98	0.06	3.2%	07-12130-00
Obstetrics RN 1	L3	15	3.98	0.13	3.3%	07-12129-00
Phlebotomist 1	L3	15	4.22	0.22	5.2%	07-12132-00
Respiratory Therapist 1	L3	15	4.31	0.22	5.0%	07-12130-00
POC Technician	L3	15	4.44	0.18	4.1%	07-12136-00
Obstetrics RN 2	L3	15	4.32	0.15	3.5%	07-12129-00
Phlebotomist 2	L3	15	4.17	0.18	4.2%	07-12129-00
Medical Technologist	L3	15	4.58	0.25	5.4%	07-12132-00
Obstetrics RN 3	L3	15	4.45	0.17	3.9%	07-12132-00

Figure 5.13 – Table – Creatinine Aqueous Precision

Chloride			
Control Fluids	**QC Level 1**	**QC Level 2**	**QC Level 3**
Total Tests			
N - Tests	165	163	148
Mean	76.5	98.6	123.7
SD	0.50	0.56	1.06
CV% Total	0.7%	0.6%	0.9%
Run-to-run			
N - Runs	11	11	10
Mean	76.5	98.6	123.7
SD	0.21	0.34	0.71
CV% R-R	0.3%	0.3%	0.6%
Within-run			
N - WR Replicates	15	15	15
Avd SD W-R	0.44	0.44	0.69
CV% W-R	0.6%	0.4%	0.6%

Creatinine			
Control Fluids	**QC Level 1**	**QC Level 2**	**QC Level 3**
Total Tests			
N - Tests	120	119	120
Mean	0.66	2.04	4.31
SD	0.05	0.13	0.27
CV% Total	6.8%	6.4%	6.3%
Run-to-run			
N - Runs	8	8	8
Mean	0.66	2.04	4.31
SD	0.02	0.01	0.02
CV% R-R	3.4%	5.5%	4.0%
Within-run			
N - WR Replicates	15	15	15
Avd SD W-R	0.04	0.08	0.21
CV% W-R	6.1%	3.8%	4.8%

Figure 5.14 – Tables – Chloride and Creatinine Aqueous Precision Summaries

5.6.4 Matrix Effects

The method comparison studies were performed in field trials at two hospitals on patient samples of whole blood at various locations. Patient specimens were venous, arterial and capillary. The method comparison was against the predicate device.

	Chloride epoc vs. i-STAT			
	Venous	**Arterial**	**Capillary**	**All**
N	49	43	63	155
Sxx	0.7	1.4	0.6	0.9
Syy	0.7	0.8	0.9	0.8
slope	1.00	0.96	1.02	0.99
intercept	-0.24	2.35	-3.06	0.20
Syx	2.5	1.9	1.3	1.9
X min	72	69	70	69
X max	136	136	139	139
R^2	0.97	0.99	0.99	0.98

	Creatinine epoc vs. Roche Cobas			
	Venous	Arterial	Capillary	All
N	53	42	49	144
Sxx	0.09	0.12	0.09	0.10
Syy	0.28	0.32	0.30	0.30
slope	1.03	1.04	1.01	1.03
intercept	-0.12	-0.11	-0.06	-0.10
Syx	0.47	0.48	0.40	0.45
X min	0.30	0.30	0.30	0.30
X max	14.50	14.30	14.80	14.80
R^2	0.99	0.99	0.99	0.99

Figure 5.15 – Table of Method Comparison Summary Against Predicate Device By Sample Matrix Type

Chloride epoc vs. i-STAT, mM			
Matrix	Decision Level	90	112
Venous	Avg. Bias	0.0	0.0
	±95% CI	0.8	0.7
Arterial	Avg. Bias	-0.9	-1.7
	±95% CI	0.8	0.4
Capillary	Avg. Bias	-1.3	-0.9
	±95% CI	0.4	0.3
All	Avg. Bias	-0.7	-1.0
	±95% CI	0.4	0.3

Creatinine epoc vs. Roche Cobas, mg/dL			
Matrix	Decision Level	1.25	1.60
Venous	Avg. Bias	-0.08	-0.07
	±95% CI	0.05	0.05
Arterial	Avg. Bias	-0.06	-0.04
	±95% CI	0.07	0.07
Capillary	Avg. Bias	-0.05	-0.04
	±95% CI	0.03	0.03
All	Avg. Bias	-0.06	-0.05
	±95% CI	0.03	0.03

Figure 5.16 – Table of Method Comparison Summary Against Predicate Device – Consolidated Bias by Sample Matrix Type

5.6.4.1 Effect of Anticoagulant

The effect of anticoagulant was evaluated on patient samples that were collected using heparinized and non-heparinized collection devices. This study was performed at a hospital (46 samples) and supplemented with in-house studies (29 samples). The data was analyzed using EP9-2A methodology.

Chloride epoc Hep vs. No-Hep	
N	76
Sxx	0.6
Syy	0.8
slope	0.98
intercept	1.92
Syx	1.2
X min	99
X max	129
R^2	0.97

Creatinine epoc Hep vs. No-Hep	
N	77
Sxx	0.26
Syy	0.33
slope	0.99
intercept	0.02
Syx	0.23
X min	0.42
X max	10.53
R^2	0.99

Figure 5.17 – Table of Heparinized Versus Non-Heparinized Samples

5.7 Summary of Conclusions Drawn from Non Clinical and Clinical Tests

We conclude from the data presented in section 5.5 that the device performs effectively. We conclude from the data section 5.6 that the clinical performance of the device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

EPOCAL Inc.
c/o Roy Layer,
Vice President, Quality Assurance & Regulatory Affairs
2060 Walkley Road
Ottawa, Ontario, Canada K1G 3P5

OCT 5 2012

Re: k113726
Trade Name: epoc Chloride test, epoc Creatinine test
Regulation Number: 21 CFR §862.1170
Regulation Name: Chloride test system
Regulatory Class: Class II
Product Codes: CGZ; CGL
Dated: September 12, 2012
Received: September 13, 2012

Dear Mr. Layer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Devices and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH'S Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-576-. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800 638-2041 or (301) 796-5680 or at its Internet address http://www.fda/gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k): k113726

Device Name: epoc Chloride test

Indication For Use:

The Chloride test, as part of the epoc Blood Analysis System, is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care.

Chloride measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113726

Indications for Use

510(k): k113726

Device Name: epoc Creatinine test

Indication For Use:

The Creatinine test, as part of the epoc Blood Analysis System, is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care.

Creatinine measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of certain renal diseases and in monitoring renal dialysis.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113726